IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

STEPHANIE A. FISHER, Individually, MARK C. FISHER, Individually, and MARLENE L. FISHER, Individually;	)	**Case No.:** _____
Plaintiffs,	)	**COMPLAINT**
v.	)	
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation;	)	**DEMAND FOR JURY TRIAL**
Defendant.	)	

COMPLAINT

Now come the plaintiffs, STEPHANIE A. FISHER, Individually, MARK C. FISHER, Individually, and MARLENE L. FISHER, Individually, and complaining against the defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE ("GSK") state:

NATURE OF ACTION

1. This is a products liability case arising out of the Paxil-induced suicide attempt by Stephanie A. Fisher on January 6, 2003 in Jamestown, New York. At the time of this event, Stephanie was under the influence of a powerful, serotonergic, psychotropic drug called "Paxil" which is manufactured and marketed by defendant GSK.

JURISDICTION AND VENUE

2. Original subject matter jurisdiction in this Court is appropriate pursuant to 28 U.S.C. § 1332 because the parties are diverse and the amount in controversy exceeds $75,000.

3. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events or omissions giving rise to plaintiffs' claims occurred in this judicial district and because GSK resides in this judicial district.

PARTIES

4. Plaintiff Stephanie A. Fisher is a competent adult and a resident of Jamestown, New York. She brings this action individually to recover her individual economic and non-economic damages resulting from her Paxil-induced suicide attempt.

5. Plaintiff Marlene L. Fisher is a competent adult and the mother of Stephanie Fisher. She currently resides in Jamestown, New York. She brings this action individually for her individual economic and non-economic damages resulting from her daughter's suicide attempt.

6. Plaintiff Mark C. Fisher is a competent adult and the father of Stephanie Fisher. He currently resides in Jamestown, New York. He brings this action individually for his individual economic and non-economic damages resulting from his daughter's suicide attempt.

7. On January 6, 2003, Stephanie Fisher attempted to commit suicide by cutting her wrist with a butcher knife. Her attempted suicide was a result of her ingestion of the prescription drug Paxil. Stephanie was 17 years old at the time of her suicide attempt.

8. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter referred to as "GSK") was and still is a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania. At all times hereinafter mentioned, defendant GSK was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Paxil (known generically as paroxetine), an antidepressant, throughout the United States.

GENERAL ALLEGATIONS

9. The drug paroxetine, is manufactured, promoted, distributed, labeled, and marketed by GSK under the trade name Paxil, Paxil Oral Suspension, and Paxil CR, and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs." Paxil was first approved for use in the United States by the FDA in 1992 for the treatment of depression in adults. It has never been approved in the United States for use by children or adolescents.

10. In 1994, GSK first began testing Paxil on children and adolescents. The first clinical trial, Study 329, was a multi-center, placebo controlled study of Paxil and imipramine for use with children and adolescents with unipolar depression. This specific study was originally proposed by Dr. Martin Keller of Brown University and his close associates, including Dr. Neal Ryan from the University of Pittsburgh. Study 329 concluded in 1998 at which time the data from the trial was analyzed by GSK.

11. The analysis of the data from Study 329 showed that Paxil was not only ineffective for the treatment of depression for children and adolescents, but, more importantly, that Paxil was associated with an increased risk of suicidality in those children and adolescents who took the drug as compared with those taking placebo. In fact, this study showed a 5.9 times increase in the risk of a suicide event for a child taking Paxil as compared with placebo. This risk ratio is consistent with the data from the pre-marketing clinical trials involving adults.

12. A second randomized, placebo controlled Paxil trial that concluded later in 1998 involving children and adolescents, Study 377, also showed that Paxil was ineffective for the treatment of depression in children and adolescents and had a twofold increase in the risk of suicide-related events as compared with placebo.

13. When confronted with these analyses, GSK acknowledged that "data from these studies are insufficiently robust to support a label change and will therefore not be submitted to the

regulatory authorities." Notwithstanding this acknowledgment, GSK outlined a course "to effectively manage the dissemination of these data in order to minimize any potential negative commercial impact." This course included publishing the sparse amount of positive data it could pull out of Study 329.

14. During this same time period, GSK conducted a third Paxil clinical trial with children and adolescents to compare the efficacy of Paxil with another anti-depressant, clomipramine. This trial, Study 511, showed that 12.7% of the children taking Paxil committed a suicidal act.

15. Dating back to the mid 1990s, GSK knew that doctors throughout the United States were prescribing Paxil to children off-label. In fact, GSK performed a marketing promotional materials feedback survey for Paxil and found that doctors wanted more Paxil 10mg samples for use with children and adolescents. GSK has acknowledged that Paxil is the second most prescribed antidepressant for use by children and adolescents.

16. GSK has numerous ways in which it can, and does, communicate with the medical community regarding the dangers of the drugs it sells, including sales visits by GSK representatives, marketing and promotional materials distributed to doctors' offices, advertisements in medical journals, on television, and in magazines, seminars and continuing education presentations, educational programs and materials at medical schools, the preparation of medical journal articles, "Dear Doctor" letters describing significant risks associated with marketed drugs, and the drug's label which is required to include risks associated with a drug.

17. The primary method GSK uses to communicate with doctors is through its sales force. By the end of the 1990s, GSK had a team of sales representatives who personally visited most, if not all, doctors in the United States on a regular basis. Internal documents show that GSK was aware that many doctors do not regularly get information regarding marketed drugs from sources such as the drug's label and medical journal articles. GSK knew that personal contact by

a sales representative was the most effective way to get important information about its drugs to these doctors.

18. GSK also communicates with doctors through lectures at conferences and symposiums. Starting in 1999, GSK held a series of conferences regarding Paxil, which it called "forums," that were attended by both members of its sales force and prescribing doctors. At these conferences, paid "opinion leaders," such as Dr. Karen Wagner, discussed the use of Paxil for treating children and adolescents. Rather than using these opportunities to properly educate the audience about the dangers of Paxil when used by children and adolescents, GSK and its paid "opinion leaders" improperly promoted Paxil for use with children and adolescents.

19. GSK followed up these conferences with news letters addressed to the GSK sales force and authored by GSK's neuroscience division which further promoted the safety and efficacy of Paxil for use with pediatric patients. In one such newsletter, issued on December 8, 1999, GSK featured Dr. Karen Wagner and her involvement with Study 329. GSK quoted her in the news letter as saying: "We can say that paroxetine has both efficacy and safety data for treating depression in adolescents." GSK's obvious purpose in distributing this information to its sales force was to ensure that doctors would receive false information regarding the safety and efficacy of Paxil for the treatment of pediatric depression.

20. Beginning as early as 1998, GSK sent "opinion leaders" around the world to promote the use of Paxil for the treatment of depression in children and adolescents. These "opinion leaders" spoke at large yearly conventions of major medical associations, including, but not limited to, the World Congress of Psychiatry Meeting in Hamburg, Germany in 1999 (poster and presentation by C. Gagiano); the Annual Meeting of the European College of Neuropsychopharmology in Paris, France in 1998 (poster and presentation by Neal Ryan, R. Berard, et al.); the New Clinical Drug Evaluation Unit (NCDEU) Annual Meeting in Boca Raton, Florida in 1998, 2000, 2001 and 2002

(posters and presentations by Karen Wagner, DA Geller, Graham Emslie, et al.); the annual meeting of the American Psychiatric Association 1998, 2000 and 2002 (posters and presentations by Martin Keller, Neal Ryan, B. Birmaher, James McCafferty, et al.); the American College of Neuropsychopharmology in 1999 and 2002 (posters and presentations by Karen Wagner, Martin Stein, R. Berard, et al.); and the annual meetings of the American Academy of Children and Adolescent Psychiatry in 1999 and 2002 (posters and presentations by Karen Wagner, James Carpenter, DA Geller, Graham Emslie, et al.). Rather than using these opportunities to spread information regarding the deadly risk of suicidality associated with Paxil use with pediatric patients and the truth that Paxil is, in fact, ineffective for pediatric patients, GSK, through its "opinion leaders," presented abstracts and posters touting Paxil as being both safe and effective for children and adolescents. Thousands of doctors around the world attended these conventions.

21. Another important method GSK could have, and should have, used to disseminate to the medical community safety and efficacy data regarding the pediatric use of Paxil was through medical journal articles. However, instead of using this medium to publish accurate information regarding the pediatric use of Paxil, GSK utilized it to spread false and misleading information about the drug when it published the results of Study 329. The 329 article, which was published in 2001, falsely asserted that Paxil was superior to placebo among "four of the parameters," including one which was identified as a "primary outcome measure." In fact, GSK knew that Paxil was not found to be superior to placebo amongst any of the "primary outcome measures." Further, the article stated that "most adverse effects were not serious," and failed to list suicide-related events as "serious." GSK knew that there was a 6 times increase in the rate of suicide-related events in study 329 as compared to placebo. However, the article listed these events as "emotional lability" and did not provide readers with the true information that three children taking Paxil in this study attempted suicide by overdose, that one engaged in "cutting" behaviors, and that one was hospitalized due to

agitation, hostility, and a paranoid reaction that was classified by the investigator as "possibly related" to Paxil. Although the article listed over 20 authors, including Martin Keller, Neal Ryan, Michael Strober, Rachel Klein, Boris Birmaher, Graham Emslie, Karen Wagner, Elizabeth Weller and several GSK employees, in fact the article was drafted and edited by Sally Laden of Scientific Therapeutics Information, Inc., a firm that was hired by GSK to prepare the manuscript. The final version of the article does not list Ms. Laden as an author nor does it identify Scientific Therapeutics Information, Inc., as having been involved in the article's preparation.

22. When the 329 article was published, GSK sent a memo to its sales representatives stating that: "Paxil demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression." (Emphasis in original). This memo went on to state that "the findings of this study [329] provide evidence of the efficacy and safety of Paxil in the treatment of adolescent depression." GSK did not discuss with its sales representatives the true results of study 329, its failure to establish efficacy, nor the deadly risks associated with Paxil use in children and adolescents. Accordingly, GSK kept its sales force in the dark about the risk of suicidality despite data that demonstrated this association.

23. GSK, like all drug manufactures, can publish and distribute what are known as "Dear Doctor" letters. These letters, which are generally sent to every physician in the United States, are designed to notify doctors about important safety concerns associated with marketed drugs such as Paxil. As early as 1998, GSK had the requisite knowledge to issue a "Dear Doctor" letter in the United States regarding the association between suicidality and Paxil when used by children and adolescents. In 2003, GSK sent out a "Dear Doctor" letter in the United Kingdom warning doctors about the increased risk of suicidality with pediatric patients. However, in the United States, GSK sent a memo to its sales force dated September 8, 2003, telling the sales representatives that even though Paxil is associated with an increased risk of suicidality in the pediatric population, they

should not pass on this information to doctors: "Although you should read the letter carefully, please do not discuss the contents with your customers." Thus, as late as 2003, GSK again directed its sales force, GSK's primary and most expensive tool used to communicate with doctors, *not* to discuss the suicidality risk with doctors.

24. Additionally, GSK could have and should have initiated changes in Paxil's prescribing information, known as Paxil's "label," after it learned in 1998 of the increased risk of suicidality associated with Paxil in pediatric patients. From 1998 through 2003, GSK misleadingly stated in Paxil's label that: "Safety and effectiveness in the pediatric population have not been established." In fact, by 1998, GSK knew that the clinical trials did *not* establish effectiveness for pediatric depression and showed an increased risk of suicidality associated with Paxil use. Furthermore, during this same time period, Paxil's label only contained the following statement about the risk of suicide: "The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs." FDA regulations during this entire time period required GSK to update Paxil's warnings whenever there existed reasonable evidence of an association between Paxil and a serious risk. Additionally, FDA's regulations allowed GSK to update Paxil's warnings without prior FDA approval to include a serious risk, such as a risk of suicidality. Notwithstanding these regulations or GSK's duty to warn independant of these regulations, GSK failed to update Paxil's label to include a suicidality warning until 2004.

25. Despite GSK's attempt to conceal these dangers from the medical community, British regulators discovered them. Not only did this discovery result in the U.K. "Dear Doctor" letter referenced above, it caused the U.K. regulators to issue a press release informing doctors in Great Britain that Paxil was not to be used for the treatment of children or adolescents.

26. The FDA, upon learning about the UK's finding of an increased risk of suicidality, issued a Talk Paper on its website dated June 19, 2003, stating that it was reviewing the data from

GSK's pediatric clinical trials. At that time, the FDA recommended that Paxil not be used for the treatment of children and adolescents with depression. GSK still did not make any effort to inform healthcare providers or patients in the United States of this serious risk.

27. On June 30, 2003, GSK responded to the FDA's request for more information regarding the alleged link between Paxil and pediatric suicidality. The data submitted by GSK showed that during the clinical trials, there was a more than 2 times increase in the risk of suicide-related events associated with Paxil usage in pediatric patients as compared to placebo. GSK still did not make any effort to inform healthcare providers or patients in this country of this serious risk.

28. That same month, GSK sent a second letter to doctors in the United Kingdom stating that Paxil was contraindicated for use with children and adolescents based on these same studies. The letter stated that "[a] recently completed programme of clinical trials in children and adolescents under 18 years of age failed to demonstrate efficacy in Major Depressive Disorder and there was a doubling of the rate of reporting of adverse events in the paroxetine group compared with placebo, including: decreased appetite, tremor, sweating, hyperkinesia, hostility, agitation, emotional lability (including crying, mood fluctuations, self-harm, suicidal thoughts and attempted suicide)." The letter stated that Paxil "should not be used in children and adolescents under the age of 18 years with Major Depressive Disorder." No such letter was sent to doctors in the United States.

29. In July of 2003, GSK warned doctors in Canada that Paxil should not be used to treat depression with pediatric patients. That warning informed doctors of the increased risk of suicide-related events occurring with Paxil. GSK did not provide this warning in July of 2003 to healthcare providers or patients in the United States.

30. In the fall of 2003, the FDA announced that the Psychopharmacologic Drugs Advisory Committee ("PDAC") would hold a meeting of its experts in February 2004, to look into the issue of SSRI-induced suicidality in the pediatric population.

31. In response to the Fall 2003 announcement by the FDA, GSK worked with the American College of Neuropsychopharmacology ("ACNP") to try to head off any unfavorable findings by the FDA. Specifically, GSK worked with eight paid consultants, J. John Mann of Columbia University, Graham Emslie, Jan Fawcett, Fred Goodwin, Herb Meltzer, Neal Ryan, David Shaffer and Karen Wagner, to prepare and release an Executive Summary entitled "Preliminary Report of the Task Force on SSRIs and Suicidal Behavior in Youth," only two weeks before the PDAC was scheduled to meet in February, 2004. Not surprisingly, that document found that "weak evidence links SSRIs to suicidal behavior in youth" and that there was "no significant increase in suicidal behavior in clinical trials of youth." The ACNP recommended the "continued use of SSRIs ... as an effective and readily available treatment against depression in youth." GSK and its consultants knew this information was false and misleading.

32. Despite the ACNP report, the PDAC meeting in February of 2004 resulted in an urgent request by the FDA's advisors for stronger warnings for Paxil regarding the risk of suicidality in pediatric patients.

33. In September of 2004, the FDA released its findings regarding the link between suicide-related events and SSRI antidepressants, such as Paxil. The FDA found that there was a class-wide link between SSRI use in pediatric patients and suicide-related events. On October 28, 2004, the FDA wrote GSK and requested that GSK add a black box warning to the Paxil label regarding this increased risk. In the letter to GSK, the FDA stated that "[a] causal role for antidepressants in inducing suicidality has been established in pediatric patients."

34. In early 2005, GSK updated Paxil's label to include a "black-box" warning, which is the strongest warning allowed by FDA regulations. That warning states:

Suicidality in Children and Adolescents

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of PAXIL or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS and PRECAUTIONS -- Pediatric Use)

Pooled analysis of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4,400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

35. Thus, prior to Stephanie Fisher's suicide attempt, GSK had the knowledge, the means, and the duty to provide Stephanie's doctor and the consuming public with a stronger warning regarding the association between Paxil and suicidality through a variety of mediums, including but not limited to labeling, continuing education, symposiums, posters, advertisements, sales calls, medical journal articles, and information disseminated in medical schools. GSK failed to provide any warning through any medium prior to Stephanie's suicide attempt.

36. Plaintiffs filed this lawsuit within the applicable limitations period of first suspecting that said drugs were the cause of the injuries described herein. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the injuries described herein at an earlier time because, at the time the injuries occurred, the cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the cause of the injuries described herein, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiffs were prevented from discovering this information sooner because GSK misrepresented, and continues to misrepresent, to the public and to the medical profession that the drugs are safe and free from serious side effects, and GSK has fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action. Additionally, on December 13, 2005, GSK agreed to toll the running of the time by which plaintiffs were required to file their claims in this matter. That agreement remained in effect until July 11, 2006.

PLAINTIFFS' CAUSES OF ACTION

I.

FIRST CAUSE OF ACTION FOR NEGLIGENCE

37. Plaintiffs incorporate herein by reference Paragraphs 1 through 79 inclusive as though fully set forth at length.

38. On or about November 15, 2002, Stephanie Fisher first began ingesting Paxil. The drug first was prescribed for Stephanie by Nurse Practitioner Carol Nelson. Stephanie ingested/consumed Paxil over an approximately 2-month period. During that time, Stephanie experienced and endured grievous pain and suffering from Paxil's side effects including, but not limited to, akathisia, out-of-the-ordinary behavior, anxiety, trembling, depersonalization, emotional blunting, agitation, withdrawal from family, and suicidal thinking. After being on Paxil for about

2 months, Stephanie, under the influence of Paxil, attempted to commit suicide by cutting her wrist with a butcher knife at her home in Jamestown, New York.

39. Stephanie's injuries described herein were caused by the negligence and misrepresentations of GSK through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing Paxil;

(b) Failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions to Paxil;

(c) Being careless and negligent in that GSK knew or should have known that Paxil was a substance known to have an association with producing life-threatening effects upon certain users including but not limited to akathisia, acts of self-harm, and violent and manic episodes;

(d) Negligently and carelessly failing to adequately warn the medical community, the general public, and plaintiffs in particular of the dangers, contra-indications, and side effects from the use of Paxil;

(e) Negligently and carelessly representing that Paxil was safe for use for the purposes intended when, in fact, it was unsafe for certain users;

(f) Negligently and carelessly promoting Paxil as safe and effective for use with pediatric patients when, in fact, it was neither safe nor effective;

(g) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer;

(h) Negligently and carelessly over promoting Paxil in a zealous and unreasonable way, even though Paxil was not approved for use with pediatric patients, without regard to the potential danger that it poses for pediatric patients.

40. Before Stephanie Fisher first took Paxil, GSK—based upon the state of knowledge as it existed at the time—knew or should have known that Paxil could be dangerous, unsafe, and ineffective for use with pediatric patients and knew or should have known that it was a substance associated with preoccupation about and acts of self-harm.

41. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Stephanie Fisher suffered serious personal injuries, including physical, mental and emotional damages.

42. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

II.

SECOND CAUSE OF ACTION FOR NEGLIGENT PHARMACO-VIGILANCE

43. Plaintiffs incorporate herein by reference Paragraphs 1 through 79 inclusive as though fully set forth at length.

44. GSK has an ongoing duty of pharmaco-vigilance. As part of this duty, GSK is required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of its marketed drugs, including Paxil. GSK continually receives reports from its own clinical trials, practicing physicians, individual patients, and regulatory authorities of adverse events that occur in patients taking Paxil and its other marketed drugs. Furthermore, GSK continues to conduct clinical trials for its marketed drugs long after the drug is approved for use. GSK has a duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information it learns, or should have learned, about its marketed drugs once that information becomes available

to GSK, whether through GSK clinical trials, other outside sources, or pharmaco-vigilance activities. Specifically, when GSK learns, or should have learned, of new safety information associated with its marketed drugs, it has a duty to promptly disseminate that data to the public. GSK also has a duty to monitor epidemiology and pharmaco-vigilance data regarding its marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

45. GSK breached this duty with respect to plaintiffs. GSK, through clinical trials and other adverse event reports, learned that there was a serious problem of suicidality associated with Paxil use in pediatric patients and failed to inform doctors, regulatory agencies, and the public of this risk. GSK had the means and the resources to perform its pharmaco-vigilance duties for the entire time Paxil has been on the market in the United States.

46. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Stephanie Fisher suffered serious personal injuries, including physical, mental and emotional damages.

47. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

III.

THIRD CAUSE OF ACTION FOR STRICT LIABILITY

48. Plaintiffs incorporate herein by reference Paragraphs 1 through 79 inclusive as though fully set forth at length.

49. At all times herein mentioned, Paxil was unsafe for some people who took it, and GSK knew or should have known that said product was unsafe.

50. At all times herein mentioned, Paxil produced serious and sometimes fatal side effects, and GSK knew or should have known that said product could be unsafe because of said side effects.

51. At all times hereinafter mentioned and before Plaintiff Stephanie Fisher's ingestion of Paxil, neither members of the medical community nor members of the general public knew of the dangers existing with respect to Paxil's administration, side effects, or inadequate testing.

52. Plaintiff Stephanie Fisher used Paxil in the manner in which GSK intended it to be used.

53. Plaintiff Stephanie Fisher used or otherwise ingested Paxil in the amounts and manner and for the purpose recommended by GSK.

54. At all times material hereto, U.S.-marketed Paxil was not accompanied by complete and proper warnings for safe, informed use; the labeling accompanying Paxil did not warn physicians in general, and plaintiffs in particular, of the dangers inherent in its use, particularly of the drug's association with violence and self-harm. Further, the labeling failed to adequately inform physicians in general, and plaintiffs in particular, that Paxil is ineffective for the treatment of pediatric patients, thus depriving physicians of necessary information needed to perform an adequate risk/benefit analysis. Furthermore, GSK failed to adequately warn doctors and the medical community of this dangerous risk using the other mediums at its disposal, including but not limited to medical journal articles, sales represenatives, Dear Doctor letters, presentations and conferences, medical school information, and all of its promotional material and activities.

55. GSK promoted and maintained Paxil on the market with the knowledge of Paxil's unreasonable risk to the public in general and specifically to plaintiff Stephanie Fisher.

56. Paxil, as used by plaintiff Stephanie Fisher, was defective and unreasonably dangerous when sold by GSK, who is strictly liable for the injuries arising from its manufacture and plaintiff Stephanie Fisher's use.

57. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Stephanie Fisher suffered serious personal injuries, including physical, mental and emotional damages.

58. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

IV.

FOURTH CAUSE OF ACTION FOR BREACH OF EXPRESS WARRANTY

59. Plaintiffs incorporate herein by reference Paragraphs 1 through 79 inclusive as though fully set forth at length.

60. At all times herein mentioned, GSK utilized packaging, journal articles, advertising media, and an outside sales force to urge the use, purchase, and utilization of Paxil and expressly warranted to physicians, plaintiffs, and other members of the general public that Paxil was effective, safe, and proper for use in pediatric patients.

61. GSK represented to the consumer who would use Paxil and to the physicians who would prescribe it—without a complete disclosure of Paxil's side effects—that Paxil was safe and efficacious for children and adolescents suffering from depression, which amounted to an express warranty of Paxil's safety and efficacy.

62. GSK knew or in the exercise of reasonable diligence should have known that Paxil had the serious side effects set forth herein and was not efficacious for the treatment of pediatric patients.

63. Plaintiffs and their doctor(s) relied on GSK's express warranty representations in the use of Paxil, but Paxil was not effective, safe, and proper for its intended use as warranted in that Paxil failed and was dangerous when put to its intended use.

64. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Stephanie Fisher suffered serious personal injuries, including physical, mental and emotional damages.

65. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

V.

FIFTH CAUSE OF ACTION FOR FRAUD

66. Plaintiffs incorporate herein by reference Paragraphs 1 through 79 inclusive as though fully set forth at length.

67. In deciding whether to prescribe a drug, doctors do a risk/benefit assessment in determining which drug to prescribe. In doing so, doctors, such as plaintiffs' doctor(s) and healthcare providers, rely on the information received about Paxil from various sources, such as journal articles, company literature and discussions with GSK sales people. Such information must be accurate and provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the information is false or misleading, the physician, such as plaintiffs' doctor(s) and healthcare providers, cannot accurately assess the crucial risk/benefit balance for the patient or exercise professional judgment that is independent. Consequently, the physician, including plaintiffs' doctor(s) and healthcare providers, cannot act in accordance with the professional and fiduciary obligations owed to the patient nor can the patient, or in this instance plaintiffs, give informed consent to the treatment.

68. Concealing adverse information and providing inaccurate or biased information that is material to a prescribing decision misleads the physician and the patient who relies on that physician's professional judgment, which is what happened with plaintiffs and their doctor(s) and healthcare providers. This misleading information, along with omissions of material facts related to Paxil's safety and effectiveness, cause healthcare providers, patients and the general public to be misled about Paxil's risks and benefits and deprives doctors of their ability to make a proper risk/benefit assessment as to the use of Paxil. In internal, unpublished documents, which have been kept from public and regulatory scrutiny via the stratagem of over-broad "confidentiality" designations, GSK has made numerous admissions about Paxil's associated harmful side effects and

lack of effectiveness in children and adolescents. Notwithstanding these admissions, in flagrant and conscious disregard and indifference to the health and safety of the consuming public, GSK has denied publicly that such nexus exists, and has failed utterly to take any measures whatsoever to alert the public, the prescribing physicians, and the patients who take it, of the incipient dangers associated with Paxil.

69. Additionally, GSK has defrauded the medical profession (including plaintiffs' doctor(s) and healthcare providers), the Paxil patient population (including plaintiffs), and the general public (including, but not limited to plaintiff Stephanie Fisher's friends and family) in that it, among other acts:

(a) Hired a firm to "ghostwrite" an article that was widely publicized which claimed, falsely, that Paxil was effective and safe for the treatment of depression with children and adolescents;

(b) Hired doctors to present "posters" around the world at medical conferences which claimed, falsely, that Paxil was effective and safe for the treatment of depression with children and adolescents;

(c) Fraudulently mischaracterized and miscoded adverse events involving self-harm with the term "emotional lability" so as to reduce the number of occurrences and hide their existence from the public and regulators;

(d) Failed to inform the medical and research communities that a significant number of pediatric patients taking Paxil during clinical trials attempted acts of self-harm at a rate that was at least twice that for pediatric patients who took placebo;

(e) Fraudulently claimed that Paxil's characteristic side effects of insomnia, agitation and anxiety were of little or no concern when in fact these effects

are known to be among the most critical and deadly of the short-term risk factors for self-harm;

(f) Fraudulently denied Paxil's association with serious or deadly thoughts or acts of self-harm when its own investigators informed GSK (and GSK determined itself) that Paxil was associated with such conditions;

(g) Aggressively promoted Paxil to doctors for use with pediatric patients even though Paxil was not, and is not, approved for use with children and adolescents;

70. When said representations and/or omissions were made by GSK, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by GSK with the intent of defrauding and deceiving the public in general and the medical community and with the intent of inducing the public to take Paxil and the medical community to recommend, prescribe, and dispense Paxil for use with pediatric patients.

71. At the time the aforesaid representations and/or omissions were made by GSK, and at the time that plaintiff Stephanie Fisher ingested Paxil, plaintiffs, her family/friends, and her medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied on GSK's assertions, promulgated through its aggressive promotional activities to her medical providers as set forth herein, that the drug was safe and effective when, in fact, it was neither.

72. In reliance upon said representations and/or omissions, plaintiff Stephanie Fisher's medical providers did prescribe Paxil and plaintiffs were induced to and did allow plaintiff Stephanie Fisher to take Paxil. Had plaintiff Stephanie Fisher or her parents known of the actual dangers of Paxil and its lack of effectiveness, through her medical providers or otherwise, she would

not have ingested Paxil, or she would have ceased taking it or otherwise sought help once its side effects (which were clearly known to GSK, but not fully disclosed to such providers or the public) became apparent.

73. GSK's motive in failing to advise physicians and the public of the adverse reactions that can increase the risk of suicide and suicidality (and that it knew a percentage of users of the drug inevitably would experience) was for financial gain and its fear that if GSK provided proper and adequate information, Paxil would lose its share of the SSRI market.

74. At all times herein mentioned, the actions of GSK, their agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of plaintiff Stephanie Fisher in particular and to the general public in that GSK did wilfully and knowingly place the dangerous and defective drug Paxil on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use indicating that Paxil is not safe and effective for use with pediatric patients.

75. At all times relevant herein, GSK's conduct was malicious, fraudulent, and oppressive toward plaintiffs in particular and the public generally, and GSK conducted itself in a willful, wanton, and reckless manner. Despite GSK's specific knowledge as set forth above, GSK deliberately recommended, manufactured, produced, marketed, sold, distributed, merchandized, labeled, promoted, and advertised the dangerous and defective drug Paxil. All of the foregoing constitutes an utter, wanton, and conscious disregard of the rights and safety of a large segment of the public. Thus GSK is guilty of reckless, willful, and wanton acts and omissions which evidence a total and conscious disregard for the safety of plaintiff Stephanie Fisher and others which proximately caused the injuries described herein. Therefore, plaintiffs request punitive and exemplary damages in an amount to be determined at trial to deter GSK from continuing its

conscious disregard of the rights and safety of the public at large and to set an example so GSK—as well as other similarly situated drug manufacturers—will refrain from acting in a manner that is wanton, malicious, and in utter, conscious disregard of the rights of a large segment of the public.

76. As a direct and proximate result of the aforesaid conduct of GSK, plaintiff Stephanie Fisher suffered serious personal injuries, including physical, mental and emotional damages.

77. As a further direct and proximate result of the aforesaid conduct of GSK, plaintiffs suffered economic and non-economic damages in excess of the jurisdictional minimum of the Court.

VI.

SIXTH CAUSE OF ACTION FOR

LOSS OF CONSORTIUM AND LOSS OF INCOME

78. Plaintiffs incorporate herein by reference Paragraphs 1 through 79 inclusive as though fully set forth at length.

79. As a result of the wrongful conduct by GSK described herein, plaintiffs Mark C. Fisher and Marlene L. Fisher suffered a loss of love, society, comfort, affection, companionship, services, and moral support in an amount to be determined at trial. Furthermore, as a result of the wrongful conduct by GSK described herein, plaintiffs Mark C. Fisher and Marlene L. Fisher suffered a loss of income in an amount to be determined at trial.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

1. For general damages in a sum exceeding this court's jurisdictional minimum;

2. For all damages as allowed by law;

3. For punitive and exemplary damages according to proof;

4. For prejudgment interest and post-judgment interest as allowed by law;

5. For the costs of suit herein incurred; and

6. For such other and further relief as this Court may deem just and proper.

Dated: July 7, 2006 Respectfully Submitted,

/s/ Cara J. Luther
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